

REMARKS

Claims 1-15 and 17-35 were pending in the application prior to this amendment. By this amendment, no claims have been cancelled, while claims 36-40 have been added in order for Applicants to more fully claim what they regard and their invention. Accordingly, Applicants present claims 1-15 and 17-40 to the Examiner for consideration.

I. INTRODUCTION

Dental bleaching compositions that include potassium nitrate within the claimed amounts are believed to have surprising and unexpected properties compared to compositions that include greater amounts of potassium nitrate. As evidenced by a comparative study described in the present application and in Preliminary Amendment "A", dental bleaching compositions that include potassium nitrate in an amount of about 0.01% to about 2% by weight, more preferably in a range of about 0.05% to about 1% by weight, and most preferably in an amount of about 0.5% by weight, possess the surprising and unexpected property of being unable to provide superior desensitization of teeth and soft tissues compared to dental bleaching compositions that include either 3% potassium nitrate or no potassium nitrate. Moreover, as evidenced by the comparative study, the inventive compositions may also provide enhanced tooth whitening compared to dental bleaching compositions that either include no potassium nitrate or 3% potassium nitrate. Both of these surprising and unexpected results are counterintuitive because one of ordinary skill in the art would not have predicted that decreasing the quantity of potassium nitrate within a bleaching composition would have the effect of increasing the ability of the potassium nitrate to counteract sensitivity caused by the bleaching agent and increasing the whitening effect of the dental bleaching composition.

II. REJECTION UNDER 35 U.S.C. § 103(a)

The Office Action rejects claims 1-15 and 17-35 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,256,402 to Prencipe et al. In making this rejection, the Office Action alleges that Prencipe et al. discloses a dentifrice comprising a peroxide compound and potassium nitrate within a concentration of about 0.1 to about 10% by weight. Based on this, and in view of the fact that the claims in the present application describe an overlapping concentration range for potassium nitrate, the Office Action alleges that the claims are *prima facie* obvious over Prencipe et al. The Office Action also alleges that the term “substantially free of abrasives” does not clearly distinguish over Prencipe et al., which the Office Action acknowledges requires the use of an abrasive.

With respect to the concentration of potassium nitrate, the Examiner appears to be correct that claiming an overlapping range of a component can result in a *prima facie* obviousness rejection. See *In re Werthheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). If there is *prima facie* obviousness, the burden then shifts to the applicant to show that the claimed ranges or proportions impart more than a difference in degree to make the invention as a whole separately patentable over the prior art. *Id.* at 267, 191 USPQ at 100. Thus, according to *In re Werthheim*, a *prima facie* obviousness rejection can be overcome in the case of overlapping ranges by showing that the claimed ranges or proportions impart surprising or unexpected results compared to the prior art.

As clearly shown by the comparative study that was conducted for various concentrations of potassium nitrate, which study is discussed in the application as well as in Preliminary Amendment “A” submitted previously, Applicants have surprisingly and unexpectedly discovered that utilizing less potassium nitrate better offsets sensitivity that is caused by the

dental bleaching agent. This is counterintuitive. If potassium nitrate acts to desensitize teeth, one would expect that increasing the level of potassium nitrate in a bleaching composition would increase the desensitizing effect. In fact, the comparative study showed that using less than 3% potassium nitrate actually increased the desensitization effect compared to using 3% potassium nitrate. This is truly a surprising and unexpected result sufficient to rebut the *prima facie* case of obviousness relative to Prencipe et al. Cf., *In re Wertheim*, 541 F.2d at 267, 191 USPQ at 100. Even more surprisingly, including potassium nitrate in lesser amounts appeared to result in increased whitening of teeth in statistically relevant samples.

By analogy, Prencipe et al. discloses the use of an abrasive. Clearly, one would expect that increasing the concentration of the abrasive would increase the abrasiveness of the dentifrice composition and that using less abrasive would decrease the abrasiveness of the dentifrice composition. In contradistinction, however, decreasing the amount of potassium nitrate in the bleaching composition does, in fact, better counteract increased sensitivity that may be caused by the dental bleaching agent. Why this happens is not well-understood. The fact that it happens is counterintuitive, as well as surprising and unexpected. Thus, the present invention is not *prima facie* obvious over Prencipe et al.

In short, there is no teaching or suggestion in Prencipe et al. to use lower amounts of potassium nitrate (*i.e.*, within a range of about 0.01% to about 2%) rather than using up to 10% potassium nitrate. The coincidental overlap of concentration of potassium nitrate as claimed in the present invention with the extreme lower end of the concentration range described in Prencipe et al. is off-set by the surprising and unexpected discovery that using potassium nitrate within the claimed ranges yields superior results compared to using potassium nitrate in the

amounts described in 80% of the range described in Prencipe et al. (*i.e.*, above about 2% to 10%).

Applicants will now discuss the patentability of the independent claims individually.

A. Claim 1

Applicants have amended independent claim 1 to delete the term “substantially” such that claim 1 now states that “the dental bleaching composition is free of abrasives”.¹ In contrast to claim 1 as amended, Prencipe et al. discloses and claims the use of an abrasive. Col. 3, line 39; col. 10, l. 9. The reason for including the abrasive is to address alleged problems associated with whitening products that do not include an abrasive, which Prencipe et al. articulates as follows:

A drawback to the use of whitening products which are formulated without abrasives is that, in addition to having a slow bleaching action, the products are not effective in stain removal. Thus, the polishing agent [abrasive] incorporated in a dentifrice acts to debride and physically scrub the external surface of teeth. This scrubbing action removes filmy bacterial and plaque layers as well as some of the stains and discoloring pigments that are found on teeth that cause the undesired discoloration. These polishing agents [abrasives] also microabrade the tooth so as to polish the teeth to give the enamel a more lustrous appearance and a higher optical sheen. This microabrasion action enhances the scrubbed teeth’s ability to reflect white light and thereby appear brighter.

Col. 2, lines 55-68.

Since Prencipe et al. so adamantly focuses on the alleged drawbacks of not including an abrasive within dental whitening products, Prencipe et al. clearly teaches away from dental

¹ The term “free of abrasives” means that the dental bleaching compositions defined by claim 1 do not include any component that provides any significant abrasive action when placed against a person’s teeth. Thus, an insubstantial quantity of a particulate filler, which in greater amounts might impart abrasive activity, is not an “abrasive” within the meaning of this term if the particulate filler does not impart any significant abrasive activity to the dental bleaching composition.

bleaching compositions that are “free of abrasives”. For this additional reason, claim 1 is believed to be patentable over Prencipe et al., either alone or in combination with any other prior art of record.²

B. Claim 17

Claim 17 has been amended to require the potassium nitrate to be “included in an amount . . . so as to result in (i) enhanced tooth whitening by said dental bleaching agent and (ii) reduced sensitivity that may be caused by said bleaching agent when the dental bleaching composition is passively maintained in contact with the person’s teeth for a time period of at least about 15 minutes”. In contrast, Prencipe et al. neither teaches nor suggests dental bleaching compositions that contain potassium nitrate within a specific range or amount so as to provide both reduced sensitivity and enhanced tooth whitening. Indeed, according to the comparative study described above, most of the concentrations of potassium nitrate described in Prencipe et al. would not achieve the results of claim 17. Moreover, Prencipe et al. discloses a tooth paste composition which, according to the recommended brushing times of the American Dental Association, is intended to remain in contact with a person’s teeth for 2-3 minutes. In contrast, claim 17 requires an amount of potassium nitrate that is able to offset tooth sensitivity that may be caused by a dental bleaching agent that remains in contact with a person’s teeth for at least about 15 minutes. For these reasons, claim 17 is believed to be patentable and unobvious over Prencipe et al., either alone or in combination with any other prior art of record.

² Since it is important for the compositions of Prencipe et al. to abrasively clean a person’s teeth, a dental bleaching composition that included a particulate filler in an amount that did not provide any significant abrasive activity would be contrary to Prencipe et al. Thus, by removing the term “substantially” from claim 1, Applicants have in nowise evinced an intent to surrender dental bleaching compositions that include an amount of a particulate filler that does not impart any significant abrasive activity.

C. Claim 18

Claim 18 recites a method for whitening and desensitizing a person's teeth that comprises the act of "contacting the person's teeth with said dental bleaching composition for a time period of at least about 15 minutes without scrubbing or brushing". In contrast, Prencipe et al. is directed to a tooth paste composition that is specifically intended to be brushed or scrubbed onto a person's teeth in order to enhance tooth whitening. *See* col. 2, ll. 55-69; col. 9, ll. 42-45. Because one of ordinary skill in the art would know that toothpaste compositions are intended to remain in contact with a person's teeth for 2-3 minutes during normal brushing, Prencipe et al. provides no teaching or suggestion that would have motivated one of ordinary skill in the art to contact a dental bleaching composition with a person's teeth "for a time period of at least about 15 minutes". Indeed, the Prencipe et al. composition was brushed onto bovine teeth using 50 brush strokes, which most likely took less than 60 seconds to complete, assuming 1 or more brush strokes per second. Col. 9, lines 42-45. For these reasons, claim 18 appears to be further patentable and unobvious over Prencipe et al., either alone or in combination with any other prior art of record.

D. Claim 28

Similar to claim 17 above, claim 28 has been amended to recite that the potassium nitrate is "included an amount . . . so as to result in (i) an increase in tooth whitening by said dental bleaching agent and (ii) a reduction in sensitivity that may be caused by said dental bleaching agent when the dental bleaching composition is maintained in contact with a person's teeth for a time period of at least about 15 minutes". Prencipe et al. neither teaches nor suggests dental bleaching compositions that contain potassium nitrate within a specific range or amount so as to

provide both reduced sensitivity and enhanced tooth whitening. Indeed, according to the comparative study described above, most of the concentrations of potassium nitrate described in Prencipe et al. would not achieve the result of claim 28. Moreover, Prencipe et al. discloses a tooth paste composition that is intended to remain in contact with a person's teeth for 2-3 minutes or less. In contrast, claim 28 requires an amount of potassium nitrate that is able to offset tooth sensitivity that may be caused by a dental bleaching agent that remains in contact with a person's teeth for at least about 15 minutes. For these reasons, claim 28 is believed to be patentable and unobvious over Prencipe et al., either alone or in combination with any other prior art of record.

E. Claim 29

Claim 29 recites a method for whitening a person's teeth comprising the acts of "introducing a quantity of said dental bleaching composition into a dental tray" and "placing the dental tray over the person's teeth in order for the dental bleaching composition to contact a person's teeth for a time period of at least about 15 minutes so as to whiten the person's teeth. In contrast, Prencipe et al. teaches away from the use of a dental tray to bleach teeth. More specifically, Prencipe et al. teaches that "[t]his method of treatment has drawbacks, including tooth sensitivity, demineralization of the person's teeth, and irritation of oral tissues". Col. 1, *ll.* 65-68. In addition, Prencipe et al. teaches that "an additional disadvantage of the tray application method is that the bleaching effect is very slow". Col. 1, *l.* 68 - col. 2, *l.* 2. Finally, Prencipe et al. neither teaches nor suggests contacting a dental bleaching composition with a "person's teeth for a time period of at least about 15 minutes". For these reasons, claim 29 is believed to be

patentable and unobvious over Prencipe et al., either alone or in combination with any other prior art of record.

F. New Claims 36-40

Applicants have added new claims 36-40 in order to more fully claim what they regard as their invention. Support for these claims is found in the existing claims. Prencipe et al. neither teaches nor suggests dental bleaching compositions comprising the specific components as recited in claim 36.

V. CONCLUSION.

Applicants believe that the application is presently in allowable form. In the event that the Examiner finds any remaining impediment to the prompt allowance of this application, which could be clarified by a telephonic interview, or which is susceptible to being overcome by means of an Examiner's Amendment, the Examiner is respectfully requested to initiate a telephonic interview with the undersigned attorney.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "VERSION WITH MARKINGS TO SHOW CHANGES MADE".

Dated this 21st day of November 2002.

Respectfully submitted,



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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Claims 1, 17, 18, 28 and 29 have been amended as follows.

1. (Twice Amended) A dental bleaching composition for whitening and desensitizing a person's teeth comprising:

at least one dental bleaching agent included in an amount so as to have a tooth whitening effect when contacted with a person's teeth;

potassium nitrate included in an amount of about 0.01% to about 2% by weight of the dental bleaching composition; and

a carrier into which said dental bleaching agent and potassium nitrate are dispersed,

wherein the dental bleaching composition is [substantially] free of abrasives.

17. (Twice Amended) A dental bleaching composition adapted for whitening and desensitizing a person's teeth [without brushing or scrubbing], comprising:

at least one dental bleaching agent included in an amount so as to have a tooth whitening effect on a person's teeth [without brushing or scrubbing the person's teeth with the dental bleaching composition];

potassium nitrate included in an amount of about 0.01% to about 2% by weight of the dental bleaching composition so as to result in [at least one of] (i) enhanced tooth whitening by said dental bleaching agent [or] and (ii) reduced sensitivity that may be caused by said dental bleaching agent when the dental bleaching composition is passively maintained in contact with the person's teeth for a time period of at least about 15 minutes without brushing or scrubbing; and

a carrier that is substantially free of abrasives into which said dental bleaching agent and potassium nitrate are dispersed.

18. (Twice Amended) A method for whitening and desensitizing a person's teeth, the method comprising:

providing a dental bleaching composition including:

a dental bleaching agent included in an amount so as to have a tooth whitening effect when contacted with a person's teeth;

potassium nitrate included in an amount of about 0.01% to about 2% by weight of the dental bleaching composition; and

a carrier into which said dental bleaching agent and potassium nitrate are dispersed,

wherein the dental bleaching composition is substantially free of abrasives; and

contacting the person's teeth with said dental bleaching composition for a time period of at least about 15 minutes without scrubbing or brushing.

28. (Amended) A dental bleaching composition for whitening and desensitizing a person's teeth comprising:

at least one dental bleaching agent included in an amount so as to have a tooth whitening effect when contacted with a person's teeth;

potassium nitrate included in an amount of about 0.01% to about 2% by weight of the dental bleaching composition so as to result in [at least one of] (i) an increase in tooth whitening by said dental bleaching agent [or] and (ii) a reduction in sensitivity that may be caused by said dental bleaching agent when the dental bleaching composition is maintained in contact with the person's teeth for a time period of at least about 15 minutes without brushing or scrubbing; and

a carrier into which said dental bleaching agent and potassium nitrate are dispersed.

29. (Amended) A method for whitening a person's teeth comprising:

(a) providing a dental bleaching composition comprising:

(i) a dental bleaching agent included in an amount so as to whiten teeth;

(ii) potassium nitrate included in an amount of about 0.01% to about 2% by weight of the dental bleaching composition; and

(iii) a carrier into which said dental bleaching agent and potassium nitrate are dispersed;

(b) introducing a quantity of said dental bleaching composition into a dental tray; and

(c) placing the dental tray over the person's teeth in order for the dental bleaching composition to contact the person's teeth for a time period of at least about 15 minutes so as to whiten the persons teeth.

New claims 36-40 have been added as follows:

36. (New) A dental bleaching composition for whitening and desensitizing a person's teeth comprising:

at least one dental bleaching agent included in an amount so as to have a tooth whitening effect when contacted with a person's teeth;

potassium nitrate included in an amount of about 0.05% to about 1% by weight of the dental bleaching composition; and

a carrier into which said dental bleaching agent and potassium nitrate are dispersed, the carrier comprising at least one tackifying agent.

wherein the dental bleaching composition is free of abrasives.

37. (New) A dental bleaching composition as defined in claim 36, the potassium nitrate having a concentration of about 0.5% by weight of the dental bleaching composition.

38. (New) A dental bleaching composition as defined in claim 36, the carrier further comprising at least one polyol.

39. (New) A dental bleaching composition as defined in claim 36, the carrier further comprising water.

40. (New) A dental bleaching composition as defined in claim 36, further comprising at least one fluoride compound.